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09/659,379	09/08/2000	Aaron I. Vinik	05126.00003	4987

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Banner & Witcoff Ltd
Eleventh Floor
1001 G Street NW
Washington, DC 20001-4597

[REDACTED] EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 07/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/659,379

Applicant(s)

Vinik et al.

Examiner
Hope Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 4, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-49 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

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DETAILED ACTION

1. Applicant's response to the Office Action mailed December 4, 2001 in Paper No. 7 on April 4, 2002 is acknowledged.
2. Claims 1, 7, 8, 10, 13-18, 23, 27, 29, 38, 45-46 and 48-49 have been amended. Claims 1-49 are pending.
3. The amendment filed April 4, 2002 does not identify claims 27 and 29 as being amended, although the claims have been amended (see 37 CFR 1.121(b) and 37 CFR 1.173, which sets forth the manner of making amendments in reissue applications), thus, the record is not clear. Clarification is required as the PTO was not instructed to amend these claims.
4. Applicant is reminded of the continuing obligation under 37 CFR 1.56 to timely apprise the Office of any litigation information, or other prior or concurrent proceeding, involving Patent No. 5,840,531, which is material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with the filing and prosecution of this application for reissue. See MPEP 1404, 1442.01 and 1442.04.

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5. It is noted that applicant submitted a substitute Declaration, however, the only signature that appears on the Declaration is for Phail Rafaeloff which renders the newly submitted Declaration as defective as there are four inventors. A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required. Thus, in accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

6. Claims 1-49 are rejected as being based upon a defective Oath/Declaration under 35 U.S.C. 251. See 37 CFR 1.175.

The nature of the defect(s) is in the failure of the Oath/Declaration to provide signatures of all the inventors.

7. The amendment filed April 4, 2002 proposes amendments to the claim 21 that do not comply with 37 CFR 1.173(c). Claim 21 has the amended material underlined in the claim, however, the entire claim should be underlined (see for example amended claim 23). Correction is required.

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Drawing

8. The formal drawings filed April 4, 2002 have been entered and approved.

9. Claims 21, 22, 27 and 28 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application. Note that claims 21, 22, 27 and 28 with the recitation of "a portion" is improper recapture for broadening. This attempt to broaden the claims which was rejected in an office action in the parent file above in the re-issue application is a clear example of recapture, which is prohibited. The claims of the issued

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patent are limited to and only enabled for SEQ ID NO: 6 and 4 (see for example Paper No. 9 of 08/741,096). Thus, this is an improper broadening of scope. In addition, these claims were specifically amended in the parent application 08/741,096 (ABN) on which 08/909,725 (Patent No. 5,804,421) claims priority as a continuation. Thus, this attempt to broaden back to the original scope is a clear case of recapture and is prohibited.

10. The response on page 6 contends that “claims 21, 22, 27 and 28 are directed to a scope which is entirely different than the claims which were rejected in the parent application. These claims are directed to different compositions of matter entirely”. This argument is not persuasive as applicant is claiming the same composition with a broader scope. Further, the rejection is based on the fact that applicant is attempting to recapture surrendered material as amendments were made in the parent file and an allowance was issued based on those amendments to get a narrower scope. Applicant also contends that “claims 27-28 are directed to methods of making expression constructs. No claims to this subject matter were previously presented. Thus there could have been no surrender of claims of this scope because they were never before presented”. This argument is not accurate as these claims are directed to methods, however, recite the “portion of” language (see for example, claim 27). Thus, the same issues found in claims 21 and 22 applies. On page 7 of the response it is stated that the reissue claims are narrower than the canceled claims, yet broader than the original patent claims, reissue must be sought within 2 years after grant of the original patent. This argument is also not persuasive as the breadth of the claims is not the issue

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but the fact that the broadening involves surrendered materials (see MPEP 1412.02).

Furthermore, applicant was not precluded from traverses the act of narrowing of the claims parent file or filing a continuation. Applicant further, contends that the portion is not an undefined portion as allegedly surrendered during prosecution. However, any “portion of” language is considered to be recapture, which was not permitted in the parent application. It is noted that the “portion” is defined by a negative limitation which describes what is lacking (signal sequence), however does not define what is required. Thus, the rejection remains.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-49 remains rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The specification discloses that the present invention is directed to a method of producing biologically active INGAP and to provide a recombinant construct for expression of biologically active INGAP, however, neither the specification nor the claims describes the INGAP activity (see for example claim 1). Further, the claims recite an islet cell neogenesis associated protein (INGAP) and the specific sequence with no limitation to the function of the protein (see claims 1, and 21). In addition, claims 21 and 27-28 recite the language “portion of” and the specific portion is not disclosed or any biological activity demonstrated or recited (see claim 29). Moreover, claim 21 is directed to oligonucleotide primers that hybridize and the claims do not recite a hybridization condition or whether this refers to high or low stringency. Furthermore, the specification does not provide any information as to the hybridization conditions and it is well known in the art the hybridization conditions vary.

As the disclosure does not adequately describe the claimed invention with respect to the hybridization conditions, the activity of the protein or any characteristics of the claimed portion, one of skill in the art would have to engage in undue experimentation to practice the claimed invention.

12. The response on page 9 states that the activities of INGAP are known in the art and applicant cites WO96/26215 and portions of the present specification. However, the claim recites “or INGAP activity” (see for example claim 1) and one of skill in the art would not be able to ascertain what specific activity is being referred to absent guidance from the specification or

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recitation of a specific activity in the claim. The specification discloses vague language such as “INGAP protein plays a role in stimulation of islet neogenesis” without providing great detail. Furthermore, the limitations of the specification cannot be read into the claims. Applicant presents an argument for the “portion of” language in the claims on page 10. Applicant has claims directed to portions of a sequence which equates to fragments without reciting functional language in the claims. Thus, to ensure that the claimed fragment/portion has the disclosed activity or has biological activity the functional language needs to be recited in the claims (applicant is directed to the Written Description Guidelines).

With regard to the recitation of the hybridization language in claim 21, applicant argues that claim 21 recites that the oligonucleotide primers hybridize to opposite strands and that specific primers are claimed that can be modified without changing function. The claimed invention is not adequately described as the claim does not presently recite the hybridization condition used to enable one skilled in the art to practice the claimed invention without undue experimentation, as it is well known in the prior art that hybridization conditions can vary and applicant by including this language in the claim has made it a limitation. Thus, the rejection remains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-12, 16, 19-21 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites “INGAP activity” without reciting what “activity” is being referred to (see claim 29). The dependent claims are included in this rejection.

Claim 6 is indefinite for the recitation of “promoter/operator” as it is unclear if the slash mark refers to “and” or “or” (see also claims 26, 34 and 41).

Claim 21 is indefinite as the claim language is ambiguous, note that applicant states that the claim is directed to primers (primers that amplify a portion consisting of nucleotides 12-456 of SEQ ID NO: 4, however, the claim can be interpreted as directed to primers that amplify a portion of INGAP, wherein the INGAP consists of nucleotides 12-456 of SEQ ID NO: 4.

14. The response on page 14 argues that the claim is definite with regard to the recitation of “activity” as the claim is to be read in light of the specification. However, this argument is not convincing as the limitations of the specification cannot be read into the claims. Further, it metes and bounds of the claim cannot be ascertained as several “activities” are disclosed.

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With regard to the rejection over claim 6, applicant contends that “promoter/operator is a term of the art. However, this argument is not convincing as the slash mark could have two different meaning, therefore, renders the claim indefinite for the ambiguity. Thus, applicant assertion that the claim language means “and” is limited as the claim could mean “and” or “or”. Therefore, the rejections have been maintained.

The Basis For Non-Statutory Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 09/717,095. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the copending application is directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence). Note also that the claims in both applications are directed to fragments (portions) of the claimed sequences. Although the claims in the two applications are not identical the claimed subject matter in both applications are an obvious variation of each other.

17. Regarding the rejection under 35 U.S.C. 103, Double Patenting, applicant's response on page 20 state that the copending application does not mention the signal sequence or teach the desirability of excluding it and the present application is directed to a sequence that lacks the signal sequence. However, this argument is not convincing as the office action clearly sets forth

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that although the claims are not identical, they are not patentably distinct from each other based on the structural similarities of the sequences and the claimed subject matter. Furthermore, both applications are directed to portions/fragments of the claimed sequences thus, are obvious variations of each other. Thus, this ground of rejection has been maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,840,531. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are directed to a recombinant construct for expression of INGAP which comprises a nucleotide sequence that encodes the amino acids set forth in SEQ ID NO: 6. Note that the patented claims are directed to an isolated DNA molecule which encodes an INGAP protein set forth in SEQ ID NO: 2 and both sequences are identical with the exception of one residue (SEQ ID NO: 6 has an additional Methionine in the beginning of the sequence). Furthermore, the present application and patent both have claims which are directed to probes, primers and antisense strands which would render each other obvious. Although the claims in the present application and the patent are not identical the claimed subject matter in both are an obvious variation of each other.

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Additionally, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP 804.

19. Applicant's response states that U.S. Patent 5,840,531 is the patent for which U.S. serial number 09/717,095 requests reissue, thus for the same reasons stated in the other double patenting rejection is applied here. However, this argument is not persuasive, because the claims in the patent are directed to an isolated DNA molecule encoding INGAP set forth in SEQ ID NO: 2 which is homologous with the sequence claimed in the instant application. Further the patented claims are directed to methods of producing the claimed protein. Thus, the rejection is relevant and remains as the two sets of claims are obvious variations of each other.

Conclusion

20. No claims are allowable.

21. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday- Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response.

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The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner


CHRISTOPHER S. F. LOW

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600